



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

125

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,692	01/11/2002	Thomas R. Cech	015389-002640US	3439
34151	7590	04/21/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW LLP 8TH FLOOR TWO EMBARCADERO CENTER SAN FRANCISCO, CA 94111			UNGAR, SUSAN NMN	
		ART UNIT	PAPER NUMBER	
			1642	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/044,692	CECH ET AL.
Examiner	Art Unit	
Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 September 2004.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 10-38 is/are pending in the application.
4a) Of the above claim(s) 1-in-part, 11-18, 19-in-part, 34-38 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,10 and 19-33 is/are rejected.

7) Claim(s) 1,10,19-21 and 29-32 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/12/04 6) Notice of Informal Patent Application (PTO-152)
7/12/04 6) Other: ____ .

Art Unit:1642

1. The Election filed September 21, 2004 in response to the Office Action of July 28, 2004 is acknowledged and has been entered. Claims 2-9 have been canceled, claims 1 and 19 have been amended and claims 21-38 have been added. Claims 1, 10, 19-20 as they are drawn to immunogenic compositions comprising human telomerase proteins, peptides and protein chimeras, 34-38 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1, 10, 19-33 drawn to immunogenic composition comprising a nucleic acid encoding SEQ ID NO:2, an immunogenic composition comprising a nucleic acid encoding a polypeptide fragment of hTRT consisting of an amino acid sequence identical to at least 20, at least 50, contiguous amino acids of SEQ ID NO:2, an immunogenic composition comprising a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein are currently under prosecution.

2. The response to the restriction requirement of July 28, 2004 has been received. Applicant's election with traverse of Group 2, claims 1, 4-5, 20 is acknowledged. The traversal is on the ground(s) that the examination of groups 5 and 6 would not impose a serious burden on the examiner since both groups are drawn to methods that incorporate the products of Group 2 in accordance with MPEP 821.04. Further, Applicant argues that claim 19 includes subject matter relevant to Groups 5 and 6 and this places claims 1, 10-13, 16, 21-33 under examination. The arguments have been considered but have not been found persuasive for the reasons previously set forth and further because the literature search, particularly relevant in this art, is not coextensive and thus different searches and issues are involved in the

Art Unit:1642
examination of each group and this represents an undue burden on the Examiner. Further, MPEP 821.04 provides for rejoinder upon the finding that product claims are allowable and as presently constituted, for the reasons set forth below, the claims are not allowable. Examiner will consider rejoining the method claims as per MPEP 821.04 if the product claims become allowable and the method claims are commensurate in scope with the allowable invention. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

It is noted that upon review and reconsideration, claims 10 and 19 have been rejoined to the elected Group 2 and that newly added claims 21-33 have been joined to Group 2 as having the same subject matter as the elected Group.

It is further noted that the limitations of claim 19 drawn to effectiveness for eliciting an immunological response are viewed as an intended use of the claimed product and therefore are not given weight in comparing the claim with the prior art. Claim 19 reads on the product *per se*, which is an immunological composition comprising a nucleic acid encoding.

3. Upon review and reconsideration and in view of the newly amended claims Examiner required further restriction of Elected Group 2 and called Michael Schiff on October 28, 2004 to ask for an oral election. Mr. Schiff elected, as per the Interview Summary appended. However, upon examining the Application, Examiner has vacated the requirement for further restriction of Elected Group 2. Thus claims 25-26 are currently examined and Applicant's telephone election is rendered moot.

Claim Objections

Art Unit:1642

4. Claims 29-32 are objected to because it appears that an inadvertent error has been made. The claims are drawn to the nucleic acid composition of claim 21, wherein the nucleic acid is a plasmid, a viral vector, an adenovirus vector, a herpes virus or an Epstein Barr Virus vector. It is noted that claim 21 is specifically drawn to an immunogenic composition comprising a nucleic acid encoding SEQ ID NO:2, encoding an immunogenic polypeptide fragment of SEQ ID NO:2 consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2, an immunogenic composition comprising a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein. Clearly, none of the nucleic acid molecules claimed in claim 21 is any of a plasmid, a viral vector, an adenovirus vector, a herpes virus or an Epstein Barr Virus vector. In particular, Examiner points to pages 55-56 of the specification wherein the constitution of vectors is described. The instant objection can be obviated, for example, by amending claims 29-32 to recite, for example, that the nucleic acid of claim 21 is incorporated into a plasmid, a viral vector, an adenovirus vector, a herpes virus or Epstein Barr Virus vector.

5. Claims 1, 10, 19-21 are objected to because they contain or are drawn to limitations not drawn to the elected invention. Appropriate correction is required.

Claim Rejections - 35 USC (112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit:1642

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

7. Claims 1, 10, 19-33 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The newly claimed limitations of an immunogenic composition comprising a nucleic acid encoding SEQ ID NO:2, encoding an immunogenic polypeptide fragment consisting of an amino acid sequence identical to at least 20, at least 50, contiguous amino acids of SEQ ID NO:2, an immunogenic composition comprising a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein have no clear support in the specification and the claims as originally filed. Applicant states that no new matter is presented in the claims as currently constituted and points to support for the claim amendments and new claims in US-2003-0096344-A1, paragraphs 0476, 0477, 0204 and 0181-0183. Applicant particularly states that the published application supports protein fragments having 100% identity with 20, 50, 100, 200 or more consecutive amino acids of TRT at paragraphs 0476-0477. This is not found persuasive since the claims are not drawn to protein fragment . Further, a review of the suggested support reveals that both of the cited paragraphs are drawn to substantial identity. In particular, paragraph 0476 is drawn to the definition of the term "substantial sequence identity," in the context of nucleic acids, wherein it is stated that substantial sequence identity refers to a measure of sequence similarity between two polynucleotides. However, neither cited paragraph refers to 100% identity with 20, 50, 100, 200 or more consecutive amino

Art Unit:1642

acids of TRT, but rather paragraph 0476 states that “It is sometimes desirable to describe sequence identity between two sequences in reference to a particular length or region (e.g., two sequences may be described as having at least 95% identity over a length of at least 500 base pairs). Usually the length will be at least about 50, 100, 200, 300, 400 or 500 base pairs, amino acids, or other residues.” The cited support is not drawn to immunological compositions comprising nucleic acids encoding specific ranges of subsequences of SEQ ID NO:2. Thus, nothing in the citation supports an immunological composition comprising a nucleic acid encoding an amino acid sequence identical to at least 20, at least 50, contiguous amino acids of SEQ ID NO:2.

In addition, Applicant states that the published application supports use of TRT fragments to elicit an immune response in mammalian subjects and points specifically to paragraph 0204 to support the newly claimed immunogenic compositions comprising nucleic acid encoding SEQ ID NO:2 and fragments consisting of at least 20 contiguous amino acids of SEQ ID NO:2. This is not persuasive because a review of paragraph 0204 reveals support only for peptides used to induce specific antibodies typically having an amino acid sequence consisting of at least five amino acids, preferably at least 8 amino acids, more preferably at least 10 amino acids. Nowhere in the cited support is there a teaching of an immunogenic composition comprising nucleic acid encoding SEQ ID NO:2 and fragments consisting of at least 20, at least 50 contiguous amino acids of SEQ ID NO:2.

Applicant specifically points to paragraphs 0181-0183 to support the newly claimed immunogenic composition comprising nucleic acid encoding wherein the nucleic acid encoding is a plasmid, a viral vector, an adenovirus

Art Unit:1642

vector, a herpes virus or an Epstein Barr Virus vector. This is not persuasive because a review of paragraphs 0181-0183 reveals that the paragraphs are drawn to expression systems for the expression of proteins. Although the claimed expression vehicles are disclosed in the paragraphs, the cited support is not drawn to immunological compositions comprising any of the disclosed expression vehicles or the expression vehicles comprising nucleic acid encoding SEQ ID NO:2 and fragments consisting of at least 20, at least 50 contiguous amino acids of SEQ ID NO:2 . Thus, even were the claims to be amended to recite that the expression vehicles comprise the claimed nucleic acid molecules, nothing in the citation supports an immunological composition comprising said expression vehicles.

Finally, Applicant does not provide support for the newly added limitation drawn to an immunogenic composition comprising a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein. Although a review of the specification reveals support for “Short stretches of hTRT protein amino acids may be fused with those of another protein, such as keyhole limpet hemocyanin” in paragraph 0204 in the published application, no support was found for an immunogenic composition comprising a nucleic acid encoding a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein.

The subject matter claimed in claims 1, 10, 19-33 broadens the scope of the invention as originally disclosed in the specification.

Art Unit:1642

8. Claims 1, 10, 19-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 1, 10, 19-33 are drawn to immunogenic composition comprising a nucleic acid encoding SEQ ID NO:2, an immunogenic composition comprising a nucleic acid encoding polypeptide fragment of hTRT consisting of an amino acid sequence identical to at least 20 contiguous amino, at least 50 acids of SEQ ID NO:2 and chimeric proteins.

The specification teaches that the invention provides a wide variety of hTRT proteins useful for induction of an anti-hTRT immune response (p. 37, lines 1-14). The specification further teaches that the invention provides a vaccine comprising hTRT polypeptide and an adjuvant (p. 7, lines 31-32), wherein it appears that the polypeptide vaccine is an immunogenic composition. The specification teaches the production of anti-hTRT antibodies by presenting hTRT protein, any portion, fragment or oligopeptide thereof that retains immunogenic properties to the immune system of an animal in a fashion determined by methods appropriate for the animal (p. 64, lines 10-35). In addition, the specification teaches that the invention provides pharmacological compositions comprising an hTRT nucleic acid or subsequence thereof (p. 7, lines 19-22) wherein these nucleic acids are useful for gene therapy (see para bridging pages 55-56).

One cannot extrapolate the teaching of the specification to the enablement of the claims because there is no teaching of how to use an immunogenic composition that produces antibodies or cytotoxic T-cells that

Art Unit:1642

specifically target the nucleic acid encoding a protein or fragment thereof.

Given that the nucleic acid that would be targeted by the immune system molecules synthesized in response to the claimed immunologic composition would be found in the nucleus of a cell, it is not clear how the immune system molecules produced with said immunogenic composition would be able to interact with their target, thus it is not clear how one would use the claimed invention. This is especially important as drawn to claim 10 which recites a “pharmaceutical composition” given that inherent to pharmaceutical compositions is an *in vivo* use thereof for the treatment of disease.

In particular, nowhere in the specification as originally filed does Applicant teach how to use the instantly claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict how the claimed invention could be used with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

9. Claims 1, 10, 19-21, 23-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth nucleic acid encoding SEQ ID NO:2, SEQ ID NO:1 and fragments thereof and therefore the written description is not commensurate in scope with the claims drawn to an immunogenic compositions comprising a

Art Unit:1642
polynucleotide encoding at least 20 amino acids/50 amino acids of SEQ ID NO:2, an immunogenic composition comprising a chimeric protein consisting of an amino acid sequence identical to at least 20 contiguous amino acids of SEQ ID NO:2 fused with an amino acid sequence of another protein.

It is noted that the recitation of “an immunogenic composition” is not considered a descriptive function for either the claimed compositions or for the claimed polynucleotide because all molecules will elicit an immune response under appropriate circumstances.

It is noted that the polynucleotide of the instant immunogenic composition is read as “comprising” the sequences specifically recited. As defined by the MPEP 2111.03, the term comprising “is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Although the phrase “consisting of” is defined by the MPEP as “excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”), the MPEP further states that when the phrase “consists of” appears in a “clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).” Thus the claimed invention is drawn to an immunogenic

Art Unit:1642

composition comprising a polynucleotide comprising a polynucleotide encoding at least 20, at least 50 contiguous amino acids of SEQ ID NO:2.

The specification discloses a polynucleotide encoding SEQ ID NO:2 and fragments thereof. The claims, as written, however, encompass immunogenic compositions comprising polynucleotides which vary substantially in length and also in polynucleotide composition. The broadly claimed genus encompasses not only compositions comprising polynucleotides which encode a polypeptide consisting of a fragment for SEQ ID NO:2 but also encompasses polynucleotides incorporating only portions of the claimed range of nucleotides.

The instant disclosure of a single species of polynucleotide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. The findings in Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) are appropriate to the instant rejection. The Court found that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Given that the specification describes only SEQ ID NO:1, polynucleotide encoding SEQ ID NO:2 it is clear that a representative number of species falling within the genus is not provided.

Further, given the undefined and apparently unlimited nature of the claimed polynucleotides, it is apparent that the immunogenic functions of

Art Unit:1642

the undefined and claimed polynucleotides are both unknown and highly varied given that the claims are not limited to an immunogenic composition that, for example, stimulates an immune response against a polynucleotide encoding SEQ ID NO:2. The claims read on an undefined immune response to an undefined polynucleotide sequence.

For the reasons set forth above, there is no description of the conserved regions which are critical to the structure and function of the genus claimed, that is an immunogenic composition comprising said polynucleotides. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, given only the disclosed sequences, given that both the structure and function of the claimed polynucleotides are highly varied, given that prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to identify the polynucleotides encompassed, one would reasonably conclude that the invention was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. Claims 1, 10, 19-33 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10, 19-33 are indefinite because the claims are drawn to an immunogenic composition. Given that the broadly written claims, wherein the antigenic polynucleotide is not limited to polynucleotide encoding SEQ ID NO:2 or a fragment thereof, the claims read on undefined nucleic acid sequences to which immune response would also be expected. The claims

Art Unit:1642 are indefinite because it is not possible to determine the metes and bounds of the patent protection sought.

Claim 10 is rejected under 35 USC 112, second paragraph because there is no antecedent basis for the term “pharmaceutical” in claim 1 from which claim 10 depends.

Obviousness-Type Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 10, 19, 21-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809. Although the conflicting claims are

Art Unit:1642

not identical, they are not patentably distinct from each other because they relate to the same inventive concept.

The claims are drawn to immunogenic compositions comprising nucleic acid encoding SEQ ID NO:2 (claims 1, 10, 19, 21-22). US Patent No. 6,093,809 claims an isolated polynucleotide consisting of the nucleic acid sequence shown in SEQ ID NO:1 which has 100% identity to SEQ ID NO:1 of the instant application which encodes SEQ ID NO:2. US Patent No. 6,093,809 specifically teaches at paragraph 156 that the present invention also relates to pharmaceutical compositions which may comprise telomerase and/or telomerase subunit nucleotides. Any of these molecules can be administered to a patient alone, or in combination with other agents, drugs or hormones, in pharmaceutical compositions where it is mixed with suitable excipient(s), adjuvants, and/or pharmaceutically acceptable carriers. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the isolated polynucleotide consisting of the nucleic acid sequence shown in SEQ ID NO:1 of US Patent No. 6,093,809 with said adjuvants (known to be stimulators of the immune system) because of the express suggestion that the invention also relates to pharmaceutical compositions containing said adjuvants and telomerase nucleotides. Further, it would be expected that the full length polynucleotide encoding SEQ ID NO:2 would be immunogenic upon administration, in combination with the suggested adjuvants, in an *in vivo* model such as rat or mouse.

13. Claims 1, 10, 19, 21-22, 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 8-10 of U.S. Patent No. 6,261,836. Although the conflicting

Art Unit:1642

claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept.

The claims are drawn to immunogenic compositions comprising nucleic acid encoding SEQ ID NO:2 (claims 1, 10, 19, 21-22). US Patent No 6,261,836 claims an isolated polynucleotide encoding the hTRT protein of Claim 1 wherein said protein is encoded by a polynucleotide having a sequence complementary to SEQ ID NO:224 which has 100% identity to SEQ ID NO:1 of the instant application which encodes SEQ ID NO:2 (claim 3) and claims said nucleic acid comprising a promoter sequence operably linked to the sequence encoding the hTRT protein (claim 4) and claims an isolated polynucleotide encoding SEQ ID NO:224 (which is 100% identical to the instant SEQ ID NO:20 (claims 8-10). Although the coding strand appears to be SEQ ID NO:224 and the instant SEQ ID NO:1 is 100% identical to that strand and not to the complement thereof, given the coding strand, one would immediately envision the complete complement thereof. No 6,261,836 specifically teaches at paragraph 153 that the present invention also relates to pharmaceutical compositions which may comprise telomerase and/or or telomerase subunit nucleotides. Any of these molecules can be administered to a patient alone, or in combination with other agents, drugs or hormones, in pharmaceutical compositions where it is mixed with suitable excipient(s), adjuvants, and/or pharmaceutically acceptable carriers. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the isolated polynucleotide consisting of the nucleic acid sequence shown in SEQ ID NO:1 of US Patent No. 6,261,836 with said adjuvants (known to be stimulators of the immune system) because of the express suggestion that the

Art Unit:1642

invention also relates to pharmaceutical compositions containing said adjuvants and telomerase nucleotides. Further, it would be expected that the full length polynucleotide encoding SEQ ID NO:2 would be immunogenic upon administration, in combination with the suggested adjuvants, in an *in vivo* model such as rat or mouse.

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 272-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
April 19, 2005